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EXAMINER

PREGLER, SHARON

ART UNIT

PAPER NUMBER

1772

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/593,990	PEYTA VI, REGIS	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharon Pregler	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-28,30-40,42-47 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-28,30-40,42-47 and 50-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Drafts, Person's Patent Drawing, Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)             | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2011 has been entered.

### ***Claim Objections***

**Claims 12-13, & 52** are objected to because of the following informalities: Dependencies on cancelled claim 2. For the purposes of this action, they are considered to be dependant on claim 1. Appropriate correction is required.

**Claims 14-15** are objected to because of the following informalities: Dependencies on cancelled claim 3. For the purposes of this action, they are considered to be dependant on claim 1. Appropriate correction is required.

**Claim 18** is objected to because of the following informalities: Dependant on cancelled claims 6. For the purposes of this action, they are considered to be dependant on claim 5. Appropriate correction is required.

**Claim 26** is objected to because of the following informalities: the claims recites "elongated bored," where it should state "elongated bores."

**Claim 57** is objected to because of the following informalities: "removable member" is inconsistent with "removable-member" recited in other claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1 & 57** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “defining with the removable chamber a reaction chamber when said microfluidic flow cell and said removable-member are in an interfaced position.” Claim 1 is directed to the microfluidic flow cell and does not positively cite a removable member as part of the microfluidic device, thus the reaction chamber is not given patentable weight. In this claim, structural limitations that are directed to the microfluidic flow cell are given weight.

Claims 18, 57, recites “A microfluidic flow cell....wherein said removable member comprises a microfluidic flow cell.” This claim is unclear regarding the ‘flow cell’ within the removable member. It is interpreted as any fluidic cavity.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim 1, 7-10, 12, 14, 20, 23, 31-36, 47, & 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. US Patent 6,878,255.***

**Regarding claim 1**, it is noted that the claim is directed to the microfluidic flow cell and does not positively cite a removable member as part of the microfluidic device, thus the reaction chamber is not given patentable weight. In this claim, structural limitations that are directed to the microfluidic flow cell are given weight and are addressed as follows:

Wang teaches in Figures 1, 4, & 34 and column 14 line 20 – column 15 line 60, a microfluidic flow cell (separation component 120) that comprises an elongate body (see

Figures 1 and 34 for elongated body shape) defining front (right in figure 34) and rear ends (left) and opposite lateral sides;

at least one reaction portion (region of channel 130) formed at least near said front end and defining with the removable-member (detection portion 140)

at least two fluid-receiving portions (reservoirs 122, 124, & 126) positioned at least near said rear end for receiving a fluid therein and being in fluid communication with said reaction chamber;

a common channel (reaction channel 130) positioned generally centrally of said elongated body and in fluid communication with said reaction chamber;

at least two separate conduits (channels 128; note that channel 128 fluidically intersects channel 130, thus separating channel 128 into at least two conduits) being in fluid communication with said common channel and extending therefrom towards a respective one of said opposite lateral sides, each said conduit being in fluid communication with a respective one of said at least two fluid-receiving portions (See layout of fluidic components in figure 34); and

a dispensing portion (outlet 132) in fluid communication with said reaction area, and with the external environment of said microfluidic flow cell, said dispensing portion comprising a dispensing channel (outlet portion of channels 130 & 132) formed within said microfluidic flow cell;

wherein when in said interfaced position, said microfluidic flow cell is adapted to allow for the fluid in said fluid-receiving portion to flow to said reaction chamber and for excess fluid in said reaction chamber to flow into the external environment via said dispensing portion (embodiments may include reservoirs on removable portion 140).

**Regarding claim 7**, the reaction area inherently comprises a reaction cavity within channel 130 (*column 7 lines 45-55*).

**Regarding claim 8**, Wang teaches the channels can be made by etching or grooves on the substrate (*column 7 lines 45-55*).

**Regarding claim 9-10**, Wang teaches fluid receiving portions 122, 124, and 126, one may be a sample, buffer, or reactant reservoir (*column 15 lines 45-50*).

**Regarding claim 12 Wang teaches the** microfluidic flow cell with the conduits formed within said microfluidic flow cell (*Figure 34 column 15 lines 30-60*).

**Regarding claim 14 Wang teaches the** microfluidic flow cell with one of the plurality of conduits formed within said microfluidic flow cell (*Figure 34, column 15 lines 30-60*).

**Regarding claim 20,** Wang teaches a plurality of fluid receiving portions in fluid communication with the common channel and reaction area (*Figure 34, column 15 lines 30-60*).

**Regarding claim 23,** Wang teaches the common channel 130 formed on the flow cell (*Figure 34, column 15 lines 30-60*).

**Regarding claim 32,** the flow cell inherently comprises a substrate.

**Regarding claims 31, & 33-34,** Wang teaches the planar substrate, or the portion with the channels or conduits, may be constructed of fused-silica, glass, other silica-based substrates, plastics, polymeric materials, elastomeric materials, and the like (*column 8 lines 1-7, PDMS is well known material in microfluidics*). The material may also be hydrophobic (claim 31, column 8 lines 23-25).

**Regarding claim 35,** Wang teaches said removable-member comprises a support (*substrate of detection portion 140 may have a reservoir at outlet 142 for reactants to flow into, column 15 lines 45-60*).

**Regarding claim 36,** Wang teaches the material may also be hydrophobic (*claim 31, column 8 lines 23-25*).

**Regarding claim 47,** Wang teaches transporting of fluid may be actuated by centrifugal force (*column 4 lines 1-5*).

**Regarding claim 57,** Wang teaches a detection substrate with outlet 142 that is in communication with separation component 120 that contains the bulk of the fluidic components in figure 34.

**Regarding claim 58,** Wang teaches the removable member comprising a support (*flat substrate of member 140*) comprising a support cavity (*cavities of portions 142 or 144*) defining reaction chamber (*may be a reservoir column 15 lines 55-60*) when in interfaced position.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

***Claims 5, 16-19, 22, 27, 28, & 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. US Patent 6,878,255 in view Mathies US 2002/0068357.***

**Regarding claims 5 & 22** Wang teaches the microfluidic flow cell above with conduits forming intersections that act as valves (*column 9 lines 15-30*) which may be a selectable and changeable valve.

Wang does not explicitly teach a valve on the flow cell, plurality of separate conduits meet at a valve for fluid communication therewith, said valve being in fluid communication with said common reaction chamber.

However, Mathies teaches control within the microfluid capillaries comprising the use of valves. (*See [0028] & [0075]*).

It is within ordinary skill in the art and would have been obvious to place a valve in the conduits, intersections, and/or channels above for the benefit of controlling fluid flow in the microfluidic device.

**Regarding claims 16 & 27** Wang teaches the microfluidic flow cell above with conduits forming intersections that act as valves (*column 9 lines 15-30*) on the flow cell.

**Regarding claims 17 & 28 Wang** does not teach a valve cavity, said valve cavity defining said valve when said microfluidic flow cell and said removable- member are in said interfaced position.

However, Mathies teaches control within the microfluid capillaries comprising the use of valves. (*See [0028] & [0075]*).

It is within ordinary skill in the art and would have been obvious to place a valve in the conduits, intersections, and/or channels above for the benefit of controlling fluid flow in the microfluidic device.

Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, valves, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claim 18, Wang teaches the** microfluidic flow cell above with the common channel formed on the microfluidic flow cell (*column 15 lines 40-60*).

**Regarding claim 19, Wang teaches** common channel 130 that inherently comprises a common channel cavity defining a common channel (*column 15 lines 45-60*).

Wang does not explicitly teach defining a common channel with a common channel cavity when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claims 50-56, Wang teaches the** microfluidic flow cell above.

Wang does not explicitly teach at least one vent said vent being in fluid communication with the ambient environment or with the respective fluidic channels, bores, conduits, or chambers.

Mathies teaches control within the microfluid capillaries comprising the use of vents. (*See figure 1, 9 [0019], [0028], [0060] & [0075]*) for the benefit of controlling fluid flow through positive and negative pressure (*[0060]*).

It is within ordinary skill in the art and would have been obvious to place a vent between the environment and reaction chamber, environment and fluid receiving portion, environment and conduit, environment and valve, and environment and dispensing portion, above for the benefit of controlling fluid flow in the microfluidic device through positive and negative pressure.

**Claims 11, 13, 15, 21, 24, 25, 26, & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. US Patent 6,878,255.**

**Regarding claim 11, Wang teaches** fluidic receiving portions 122, 124, & 126 that inherently comprises a fluid receiving cavity defining a fluid receiving chamber (*column 15 lines 45-60*).

Wang does not explicitly teach defining a fluid receiving chamber when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claims 13 & 15, Wang teaches** conduits 128 inherently comprising a conduit cavity defining a conduit (*column 15 lines 45-60*).

Wang does not explicitly teach defining a conduit cavity when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claim 21 & 25,** Wang teaches conduits meeting at the central common channel (*column 15 lines 45-60, figure 34*).

Wang does not explicitly teach a pair of bores that meet at the central channel formed within the flow cell.

However, Wang suggests that there may be a plurality (more than two) channels or conduits (bores) on the fluidic chip (*column 9 lines 5-20*) or a multiplicity of channels or fluid conduits, such as three or more, meet at a given point, and are thereby in fluid connection one with the other. The intersection forms a cavity well or reservoir.

Therefore, it would have been obvious to one of ordinary skill in the art to add an extra pair of channels, thus have four channels meeting at the common center channel where one pair is considered as the conduits and the other pair is considered as the bore, for the benefit of adding additional reactants or buffer material to meet at the common central channel.

**Regarding claim 24, Wang teaches** common channel 130 that inherently comprises a common channel cavity defining a common channel (*column 15 lines 45-60*).

Wang does not explicitly teach defining a common channel with a common channel cavity when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would

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have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claim 26, Wang teaches** bore channels that inherently comprises a bore channel cavity defining a bore channel (*column 15 lines 45-60*).

Wang does not explicitly teach defining a bore channel when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Regarding claim 30, Wang teaches** a dispensing channel outlet 132 that inherently comprises dispensing channel outlet cavity defining a dispensing channel outlet (*column 15 lines 45-60*).

Wang does not explicitly teach defining a dispensing channel outlet when microfluidic flow cell and removable member are in said interfaced position.

However, Wang suggests in column 15 lines 40-60 that chambers and outlets are formed when component 120 is interfaced with component 140. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate other fluidic components to be formed when the two parts are interfaced in order for fluids to interact and be collected on the respective substrate when separated.

Therefore, Wang suggests to one of ordinary skill in the art to have a channel, chamber, or fluidic conduits formed with two substrates are interfaced together.

**Claims 37-40, & 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Chen et al. US 2003/0087292.**

**Regarding claims 37 & 39-40** Wang teaches the support as detection portion 140.

Wang does not explicitly teach a functionalized glass surface (**claim 37**) that's a microarray (**claim 39**) with bioprobe spots (regarding **claim 40**).

Chen teaches an array of probes deposited on a surface of the substrate; and a cover having a channel (*figure 42 shows other embodiments of the channel structure including pluralities of channels*) being coupled to the substrate such that a target fluid flowing through the channel cavity contacts each probe in the array of probes ([0014]) for the benefit of targeting molecules within a small area ([0004]). (See Chen [0004-0005], [0014-0015], [0070-73] Figures 1-2 & 42).

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the microarray and probe spots with the flow cell of Wang and place the array at the reaction portion or downstream the channel 130 for the benefit of targeting molecules within a small area.

**Regarding claim 38** Wang teaches the microfluidic flow cell above that may be glass (*column 8 lines 1-7*).

**Regarding claims 42** Wang teaches the microfluidic flow cell comprising a separation component 120 including reservoirs 122, 124 and 126 (fluid receiving portions), connected by channel 128. This embodiment may also include a waste or detector reservoir (*column 15 lines 45 -60*).

**Regarding claims 43-44** Wang teaches the plurality of channels (128, 130).

Wang does not explicitly teach access to individual spots in a microarray (**claim 43**) access to individual group spots in a microarray (**claim 44**).

Chen teaches an array of probes deposited on a surface of the substrate; and a cover having a channel (*figure 42 shows other embodiments of the channel structure including pluralities of channels*) being coupled to the substrate such that a target fluid flowing through the channel cavity contacts each probe in the array of probes ([0014])

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for the benefit of targeting molecules within a small area ([0004]). (See *Chen* [0004-0005], [0014-0015], [0070-73] *Figures 1-2 & 42*).

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the microarray and probe spots with the flow cell of Wang and place the array at the reaction portion or downstream the channel 130 for the benefit of targeting molecules within a small area.

***Claims 45 & 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of in view of Guigan US Patent 4,788,154.***

**Regarding claim 45 & 46, Wang teaches** the microfluidic flow cell above.

Wang does not teach an enclosure (regarding **claim 45**) that comprises a removable seal (regarding **claim 46**).

In the analogous art of microfluidic devices, Guigan teaches a removable cover (*lid 18, figure 2*) for the benefit of removing and reattaching the cover to the device for analysis or cleaning.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the cover of Guigan with the device of Mathies for the benefit of removing and reattaching the cover to the device for analysis or cleaning.

### ***Response to Arguments***

Applicant's arguments, see pages 9-10, filed 4/6/11, with respect to the rejection(s) of claim(s) 1 under Mathies in view of Herst have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wang, as necessitated by amendment.

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### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Mon - Fri 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571)272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/  
Examiner, Art Unit 1772

/Brian J. Sines/  
Primary Examiner, Art Unit 1772